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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,498	08/16/2001	Emmanuel Lazaridis	114205.204	2508
21901	7590	08/11/2004	EXAMINER	
SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/14

# Office Action Summary

Application No.

09/913,498

Applicant(s)

LAZARIDIS, EMMANUEL

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-15, and 18-24 is/are rejected.
- 7) ☒ Claim(s) 2, 5, 12 and 16 is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' arguments, filed 5/24/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **NEW MATTER**

Claims 1-3, 18, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been added via amending, filed 5/24/04.

In claim 1, line 4, part (a), has been amended to require the providing of observations which are "related" to objects in contrast to the previous form of the claim wherein the observations are "on the objects". Such relatedness is broader than the "on the objects" limitation due to being inclusive of observations that are not "on the objects" but on other objects which are unrelated to "the objects" of claim 1, part (a). This broadening is NEW MATTER. This NEW MATTER is also present in claims which depend directly or indirectly from claim 1 due to their dependence. This rejection is necessitated by amendment.

### **NON-STATUTORY SUBJECT MATTER**

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 11, 12, 19, 20, 22, and 24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is maintained and reiterated from the previous office action, mailed 2/24/04, and as necessitated by amendment due to newly added claim 24. Applicant argues that the amending of claim 1 is directed to responding to this rejection. In response the amending of claim 1 lacks anything other than data manipulation as previously stated as the basis for this rejection. For example, the identifying of at least one object of interest is simply data annotation and thus is non-persuasive regarding this rejection. Similarly, the argued claim 4 identifying is also only annotation of data which is reasonably annotation data manipulation and remains non-statutory. Claim 16 is argued as being directed to screening which includes a step of exposing a cell to a drug and is no longer included in this rejection as being persuasively statutory subject matter. Claims 13-18, 21, and 23 also are deemed to require a providing or manipulation of material which is statutory.

#### **VAGUENESS AND INDEFINITENESS**

Claims 1-3, 5, 12, 18, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained and reiterated from the previous office action, mailed 2/24/04, and as necessitated by amendment due to newly added claim

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24. Applicant argues that the claims should be interpreted in light of the specification but give no such specification light to rely on. Thus, this argument is not directed to factual basis and thus is non-persuasive therefore the bases for this rejection remains present, for example, in that the formula entered into claim 2 is not fully described as to parameters therein, such as "K" etc.

Also, claim 1 has been amended to delete a formula step for identifying in step (C) and now indicates identifying without setting forth any metes and bounds of such identifying. This added unclarity issue has been necessitated by amendment.

### **PRIOR ART**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-15, 19, and 21-23 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Cabib et al. (P/N 5,784,162).

This rejection is maintained and reiterated from the previous office action, mailed 2/24/04. Applicant argues that the reference does not describe analyzing protein expression data. In response Cabib et al. previously was noted as

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describing imaging especially in column 6, lines 28-34. Review of this section reveals that the reference does describe mapping of emission spectra of biological components such as hemoglobin and melanin which are expressed proteins and thus maps or images protein expression data. Proteins are present in such images via expression. Applicant points to mRNA level etc. discussion in the instant specification but does not point to any definition of what is meant by protein expression to limit it to such mRNA level analysis. Thus, applicant has therefore not persuasively argued any claim limitation which distinguishes over the basis for this rejection. Instant claims 19 and 21-23 remain rejected based on the above noted limitations and as previously stated in the office action, mailed 2/24/04, due to said instant claims being inclusive of the same subject matter as set forth as the basis for this rejection and not argued as being distinguished in the instant claims over said reference basis. For example, instant claim 21 is directed to genetic data differentiation between cancer from healthy tissue as previously set forth in the office action, mailed 2/24/04.

### **OBJECTIONS**

The disclosure is objected to because of the following informalities:

Claims 2, 5, and 12 are objected to due to subscripts being so small in the formula therein set forth as to be unreadable.

Appropriate correction is required.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Applicant requested a telephone call, however, the above issues are deemed too complex to be easily resolved thereby. Applicant, however, may call the Examiner for an Interview if desired.

Claim 17 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 8, 2004

*Adrian J. Mancini* 8/8/04  
Tina Plunkett  
Legal Instrument Examiner